DOCKET NO.: NIHA-0238 PATENT

Application No.: 10/566,540 **Office Action Dated:** June 24, 2011

REMARKS

Claims 2-5, 7, 9, 11, 13, 23, 27-52, and 54-63, directed to non-elected subject matter, have been canceled without prejudice. The Applicants reserve the right to file the canceled subject matter in one or more continuing or divisional applications.

Claims 1, 24, and 53 have been amended to recite elected subject matter. The Applicants reserve the right to file the canceled subject matter in one or more continuing or divisional applications.

Claim 6 has been amended to recite, that the PEDF-R polynucleotide of claim 1 encodes a polypeptide having an equilibrium association constant of at least 10⁴ M⁻¹ for the PEDF-R polynucleotide-PEDF interaction. Support for the amendment can be found throughout the specification, for example, at paragraph [0108].

Claim 12 has been amended to recite an isolated polynucleotide comprising a nucleotide sequence having at least 85%[[60%]] identity to SEQ ID NO: 2 or a complement thereof and that encodes a polypeptide having PEDF-R activity.

Claims 64-66 are new and depend from claim 12. Support for the new claims can be found throughout the specification, for example, at paragraph [0056].

The present invention is directed to, among other things, isolated PEDF-R polynucleotides having the sequence of SEQ ID NO: 2 and encoding a polypeptide having PEDF-R activity; or (d) a polynucleotide that hybridizes under stringent hybridization conditions to (a) and has at least 12 contiguous bases identical to or exactly complementary to SEQ ID NO: 2. Also claimed are isolated polynucleotides comprising a nucleotide sequence having at least 85% identity to SEQ ID NO:2 or a complement thereof an that encodes a polypeptide having PEDF-R activity, are also claimed are polynucleotides comprising a nucleotide sequence having at least 85% identity to SEQ ID NO:2 or a complement thereof an that encodes a polypeptide having PEDF-R activity. Methods, host cells, and vectors incorporating the claimed sequences are also described.

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Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 6, 12, 14-22, 24-26, and 53 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not complying with the written description requirement. While the applicants do not necessarily agree, in light of the present amendments directed to SEQ ID NO 2, and sequences having 85% or greater identity, the rejection is considered moot.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 6, 12, 14-22, 24-26, and 53 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. The office alleges that the "claims are unclear because a polynucleotide that hybridizes to an encoding sequence, or is complementary to an encoding sequence, cannot itself encode a polypeptide having PEDF-R activity or be identical to that sequence, because it is by definition an antisense or complementary sequence that does not encode any polypeptide." Claim 1 has been amended to recite "An isolated PEDF-R polynucleotide, wherein said polynucleotide is (a) a polynucleotide that has the sequence of SEQ ID NO: 2 and encodes a polypeptide having PEDF-R activity . . ." Reconsideration and withdrawal of the rejection is requested.

Rejections under 35 U.S.C. § 102

Claims 1, 6, 8, 10, and 12 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Mammalian Gene Collection (MGC) Program Team (PNAS, vol. 99, 2002, pages 16899-16903) ("MGC"). Applicants assert that the office has failed to meet its burden in establishing that the claims are anticipated by MGC and reconsideration and withdrawal of the rejection is requested.

It is axiomatic that anticipation requires that "each and every limitation is found either expressly or inherently in a single prior art reference." *King Pharms, Inc. v. Eon Labs., Inc.*, 616 F.3d 1267, 1274 (Fed Cir. 2010). Moreover, "anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation." *Id.* Furthermore, "[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate." *Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir.

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2003). "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Id.* As such, in order to anticipate a claim, "a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipated subject matter." *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed Cir. 1996).

It is undisputed that MGC only describes a sequence. MGC fails to describe how to make or use the described sequence. MGC fails to describe the claimed PEDF-R at all. As a result, MGC is a non-enabled reference that fails to anticipate the claimed invention. Withdrawal of the rejection is requested.

Claims 1, 6, 12, 14-22, 24-26, and 53 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 01/07628 ("Tang"). Applicants disagree. The present invention is directed to pigment epithelium derived factor (PEDF) receptor and polynucleotides that encode for a polypeptide having PEDF-R activity, among other things. In contrast, Tang is directed to human synthetases (SYNT) and polynucleotides which identify and encode SYNT.

In order to anticipate a claim, "a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipated subject matter." *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed Cir. 1996). Tang fails to disclose every element of the claims. Moreover, Tang fails to enable the skilled person to make the claimed subject matter. Withdrawal of the rejection is requested.

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